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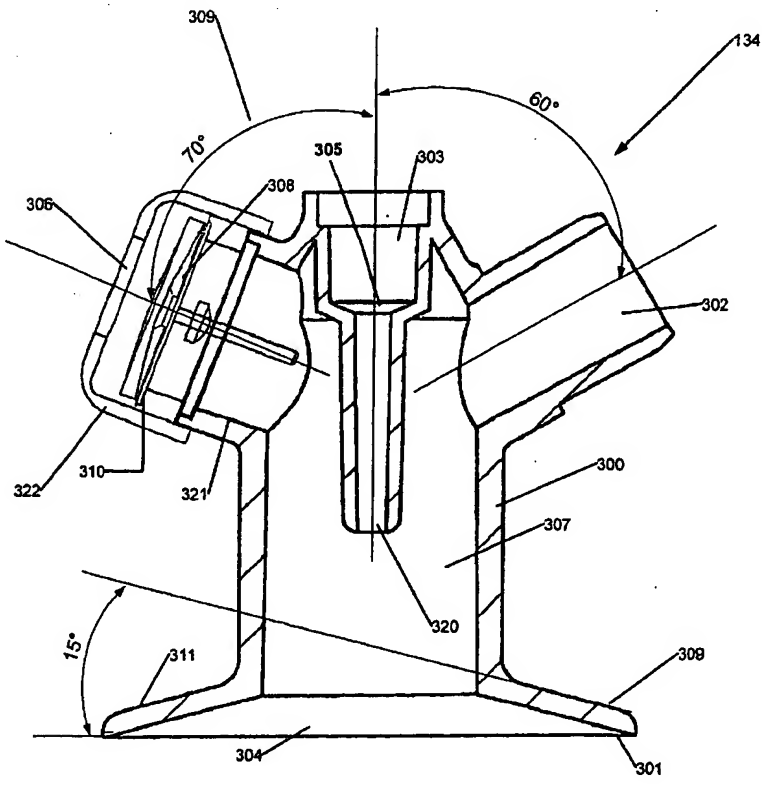
(54) Title: BREATHING ASSISTANCE APPARATUS



(57) Abstract: A connector for resuscitating an infant or neonate is disclosed. The pressure is varied between Peak Inspiratory Pressure (PIP) and Peak End Expiratory Pressure (PEEP) by the occlusion of the PEEP outlet. The PEEP outlet may either allow variable PEEP, by adjustment, or substantially flow independent fixed PEEP using a novel umbrella valve (308). A duck billed valve (305) is included for suctioning of surfactant delivery during resuscitation. The connector (134) is adapted to one handed use.

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"BREATHING ASSISTANCE APPARATUS"

FIELD OF INVENTION

The present invention relates to the use of a pressure regulator in conjunction with a breathing assistance apparatus, particularly though not solely, for regulating the pressure of gases supplied to a patient from a Positive End Expiratory Pressure (PEEP) apparatus or for an infant resuscitation device.

BACKGROUND

At the moment of their first breath, a baby's lungs are collapsed and filled with fluid. The pressures needed to open such lungs, and keep them open, are several times that of a normal breath until the fluid is displaced and the lungs have filled with air. To generate these large pressures, the baby must have strong respiratory muscles, as well as a chemical called surfactant in their alveoli. Surfactant reduces the surface tension of the fluid within the alveoli, preventing the alveolar walls from sticking to each other, like coasters to coffee cups when there is water between them.

Neonates have difficulty in opening their lungs and keeping them open. Reasons for this include:

a) Weak respiratory muscles and low surfactant levels. This means that they cannot generate enough pressure to open the lungs and, should they be resuscitated, tire quickly with the effort of keeping open alveoli lacking in surfactant.

b) Underdeveloped internal tissue structure to support the alveoli.

c) Slower clearance of lung fluid. In very premature neonates, fluid may continue to be secreted in the alveoli even after birth.

d) A soft chest wall, horizontal ribs, and a flatter diaphragm contribute to reduce the inspiratory capacity.

e) The mixing of oxygenated and deoxygenated blood raises blood pressure in the lungs, increasing fluid movement from the blood vessels into the lung tissue. The reduced blood oxygen level starves tissue of oxygen and further weakens respiratory muscles.

f) Weak neck muscles and a lack of neck fat reduce upper airway stability so that collapse on inspiration may occur.

g) Collapsed, damaged alveoli secrete proteins that reduce surfactant function.

To alleviate this it is known to apply Positive End Expiratory Pressure (PEEP) during respiration, resuscitation or assisted respiration (ventilation). In applying PEEP, the neonate's upper airway and lungs are held open during expiration against a pressure that stops alveolar collapse. Lung fluid is pushed back into the circulating blood, alveolar surfactant is conserved, and a larger area of the lung participates in gas exchange with the blood. As blood oxygenation and carbon dioxide removal improves, more oxygen is delivered to growing tissues, while less oxygen and energy is consumed by respiratory muscles. In the case of resuscitation or ventilation the pressure is varied between a Peak Inspiratory Pressure (PIP) and the PEEP value until the patient/infant is breathing spontaneously.

In order to provide the PEEP across a range of flow rates, some method is required to regulate the pressure. It is known in the art to provide a valve near the infant, which actuates at a level of pressure (ie: the PEEP value) to allow the gases to vent externally. Such valves may employ a spring-loaded valve, which in turn requires the use of high quality springs, which have been individually tested to give a high tolerance spring constant in order to ensure that it actuates at a value substantially that of the maximum safe pressure. Both the manufacture and testing of such a spring necessitates that its cost will be correspondingly high. Accordingly it would be advantageous to provide a pressure relief valve for a breathing assistance system which did not involve the use of such a high tolerance spring.

Also such valves are known to have substantial variation of the relief pressure with flow rate. For example as seen in Figure 5 the delivered pressure is shown for a range of valves. Over a given range of flow rates 50 a variable orifice 52 gives a wide range of delivered pressure. An improvement on this is a prior art umbrella valve (for example the "umbrella check valve" manufactured by Vernay Laboratories Inc. shown in Figures 4a & 4b) which delivers a lower variation 54 in delivered pressure. However in all cases the variation in delivered pressure of prior art valves would desirably be reduced for this

application.

SUMMARY OF INVENTION

It is an object of the present invention to provide a pressure regulator which goes some way to achieving the above-mentioned desiderata or which will at least provide the Healthcare industry with a useful choice.

Accordingly, in a first aspect, the present invention consists in a pressure regulating device for use with a breathing assistance and/or resuscitation apparatus which conveys gases to an infant or neonate requiring resuscitation and/or breathing assistance, comprising or including:

a housing including an inlet and an outlet and an aperture, said inlet adapted to be in fluid communication or integrated with a breathing assistance and/or resuscitation apparatus and said outlet adapted to be in fluid communication with an infant,

a valve member disposed within said housing means, in the flow path between said inlet and said venting aperture, wherein the pressure of gases being below a predetermined level said valve member at least partially blocking said aperture and said gases thereby flowing from said inlet to said outlet, and wherein said gases being above said predetermined level said valve member allowing at least a portion of said gases to flow through said vent aperture,

wherein said predetermined level is substantially independent of the rate of flow of gases from said inlet to said outlet.

Preferably said valve member comprises an elastomeric member including at least two configurations; in a first configuration substantially against a portion of said housing (herein the "valve seat") and a second configuration substantially spaced from said valve seat allowing a portion of the flow of gases from said inlet and/or said outlet to said aperture.

Preferably said portion relative to the flow at said inlet is proportional to the level of flow at said inlet, thereby regulates the pressure at said outlet to a level substantially independent of flow rate.

Preferably said elastomeric member adapted to switch from said first configuration to said

second configuration at said predetermined level.

Preferably said elastomeric member adapted such that as the flow rate increases in said second configuration a proportionally larger portion of the flow at the inlet is passed through said venting aperture then said outlet, to regulate the pressure at said outlet to substantially said predetermined level.

Preferably said elastomeric member having a shaft adapted to engage said housing and a flap having a distal end adapted to engage said valve seat, said shaft attached to or integral with a proximate end of said flap, said proximal end being thinner in cross sectional width than said distal end.

Preferably said elastomeric member is integrally molded from liquid silicon.

Preferably the ratio of said proximal end thickness to said distal end thickness is 2:3.

Preferably said shaft includes an annular flange adapted to retain at least said proximate end in relation to said aperture.

Preferably said device further comprising an occlusion opening in fluid communication with said aperture, the occlusion (or absence thereof) of said opening varying the delivered pressure to an infant between a desired PIP and PEEP respectively, said PEEP corresponding to said predetermined level.

In a second aspect the present invention consists in a device for use with a breathing assistance apparatus which conveys gases to an infant or neonate requiring resuscitation and/or breathing assistance, comprising or including:

a housing including an inlet and an outlet and an aperture, said inlet adapted to be in fluid communication or integrated with a breathing assistance and/or resuscitation apparatus and said outlet adapted to be in fluid communication with an infant, and

wherein said aperture adapted to receive a surfactant delivery means, and

sealing means adapted to prevent gas flow through said aperture and allow surfactant to be delivered to a patient through said aperture while providing breathing assistance.

Preferably a pressure relief valve is in the flow path between said inlet and said venting aperture.

Preferably said housing has a flange connected to the outlet to the patient such that in use the system can be manually operated one handed by an operator.

Preferably said pressure relief valve comprises an elastomeric member including at least two configurations a first configuration substantially against a portion of said housing (herein the "valve seat") and a second configuration substantially spaced from said valve seat allowing a portion of the flow of gases from said inlet and/or said outlet to said aperture.

Preferably said portion relative to the flow at said inlet is proportional to the level of flow at said inlet, thereby regulates the pressure at said outlet to a level substantially independent of flow rate.

Preferably said elastomeric member adapted to switch from said first configuration to said second configuration at said predetermined level.

Preferably said elastomeric member adapted such that as the flow rate increases in said second configuration a proportionally larger portion of the flow at the inlet is passed through said venting aperture then said outlet, to regulate the pressure at said outlet to substantially said predetermined level.

Preferably said sealing means is a duck billed valve.

Preferably said aperture adapted to receive a surfactant delivery means and said outlet are substantially coaxial.

In a third aspect the present invention consists in a pressure regulating device for use with a breathing assistance and/or resuscitation apparatus which conveys gases to an infant or a neonate requiring resuscitation and/or breathing assistance, comprising or including:

a housing including an inlet and an outlet and an aperture, said inlet adapted to be in fluid communication or integrated with a breathing assistance and/or resuscitation apparatus and said outlet adapted to be in fluid communication with an infant,

wherein said aperture is adapted to block or to vent or adapted to enable blocking or venting of a variable portion of gases passing through said housing from said inlet to said outlet through said aperture, and

a flange connected to said outlet adapted to engage a cushion or other means for substantially sealing the flow of gases to an infant or a neonate.

Preferably said valve member comprises an elastomeric member adapted to lie in a first configuration substantially against a portion of said housing (herein the "valve seat") and by application of an external force a second configuration where said elastomeric member allowing a portion of the flow of gases from said inlet and/or said outlet to said venting aperture.

Preferably said portion relative to the flow at said inlet is proportional to the level of flow at said inlet, thereby regulates the pressure at said outlet to a level relatively independent of flow rate.

Preferably said elastomeric member adapted to switch from said first configuration to said second configuration at said predetermined level, said external force comprising the pressure of the gases flowing from said inlet to said outlet.

Preferably said elastomeric member adapted such that as the flow rate increases in said second configuration a proportionally larger portion of the flow at the inlet is passed through said venting aperture then said outlet, to regulate the pressure at said outlet to substantially said predetermined level.

Preferably said housing also includes an aperture adapted to receive a surfactant delivery means and sealing means adapted to in use allow surfactant to be delivered to a patient through said aperture without said aperture fluidicly communicating with said interior of said housing while providing breathing assistance.

Preferably said sealing means is a duck billed valve.

Preferably said aperture adapted to receive a surfactant delivery means and said outlet are substantially coaxial.

Preferably said housing is substantially cylindrical.

Preferably said housing is part cylindrical and part frustoconical.

Preferably the width of said housing at said flange is less than the height of said housing.

To those skilled in the art to which the invention relates, many changes in construction and widely differing embodiments and applications of the invention will suggest themselves without departing from the scope of the invention as defined in the

appended claims. The disclosures and the descriptions herein are purely illustrative and are not intended to be in any sense limiting.

The invention consists in the foregoing and also envisages constructions of which the following gives examples.

BRIEF DESCRIPTION OF THE DRAWINGS

One preferred form of the present invention will now be described with reference to the accompanying drawings in which:

Figure 1 is a block diagram showing a typical configuration for supplying breathing assistance to a neonate,

Figure 2a is a sectional view of the pressure regulator according to the preferred embodiment of the present invention,

Figure 2b is a perspective view of the valve member according to the preferred embodiment of the present invention,

Figure 3 is a dimensioned side view showing hidden detail of the valve member according to the preferred embodiment of the present invention,

Figure 4a is a cross-section of a prior art umbrella valve

Figure 4b is a perspective view of a prior art umbrella valve

Figure 5 is a graph comparing pressure ranges of different valves over a flow range of 5-15 litres/minute.

Figure 6 is a sectional view of the pressure regulator according to a further embodiment of the present invention.

Figure 7 is a perspective view of the pressure regulator according to a further embodiment of the present invention.

Figure 8 is a front elevation of the pressure regulator according to a still further embodiment of the present invention.

Figure 9 is a perspective view of the pressure regulator according to a still further embodiment of the present invention

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention includes a connector for resuscitating an infant or neonate. The delivered pressure is varied between Peak Inspiratory Pressure (PIP) and Peak End Expiratory Pressure (PEEP) by the occlusion of the PEEP outlet. The PEEP outlet may either allow variable PEEP, by adjustment, or substantially flow independent fixed PEEP using a novel umbrella valve. A duck billed valve is included for suctioning of surfactant delivery during resuscitation. The connector is adapted to one handed use. The fixed PEEP valve avoids the need for adjustment as flow changes and provides more effective therapy.

Referring now to Figure 1 in which a typical application is depicted. A Positive End Expiratory Pressure (PEEP) system is shown in which an infant 119 is receiving pressurized gases through a nasal mask 128 (or endotracheal tube or other interface as are shown in the art) connected to an inhalatory conduit 121, preferably for resuscitation. Either the mask 128 or the inhalatory conduit 121 can include the pressure regulator 134 to control the pressure of gas delivered to the infant. The inhalatory conduit 121 is connected to the outlet of a resuscitator apparatus 115, which is in turn connected to a flow regulator and air supply 118 (which provides gas to the resuscitator at 50 psi or thereabouts).

It should be understood that the present invention, however, is not limited to resuscitation, or the delivery of PEEP gases but is also applicable to other types of gas delivery systems

Pressure Regulator

In the preferred embodiment of the present invention the pressure regulator 134, is shown in Figures 2 and 3 in detail. In the preferred embodiment the regulator 134 is disposed within the mask 128 although it will be appreciated that it can be allocated in a separate assembly, so long as it is proximate the infant.

Referring particularly to Figure 2a we see the preferred embodiment of the pressure regulator 134. The pressure regulator 134 includes a manifold 300 with an inlet 302 and two outlets. A first outlet 304 supplies the respiratory gases to the infant. A second outlet 306 is an external orifice as described previously to vary pressure between the PIP and

PEEP. Located between the inlet 302 and the orifice 306 is the PEEP valve 308 according to the present invention.

The PIP is adjusted at the resuscitator 115 to a desired level. The delivered gases are varied between the PIP with orifice 306 near the infant occluded, and the PEEP with the orifice 306 unoccluded. In this fashion resuscitation of an infant can be attempted by varying between the PIP and PEEP at the normal rate of breathing.

The purpose of the PEEP valve 308 according to the preferred embodiment of the present invention is to keep the Positive End Expiratory Pressure (PEEP) at a reasonably constant level independent of changes in flow rate.

Desirably for infant respiratory assistance the PEEP value should be approximately 5 cmH_20, independent of the flow rate. Preferably the interface needs to be simple and cost effective, as it is a single-use product. Also, due to the nature of this application, a valve with many small separate parts, such as a spring valve, is not a viable option.

The present invention includes a small umbrella valve 308 made of an elastomeric material, positioned on a valve seat 310 seen particularly in Figure 2a & 2b Preferably this valve is included as part of the nasal mask or endotracheal tube. As the flow rate increases, the umbrella valve flaps 312 lift up thereby letting more air out underneath and therefore keeping the pressure inside the manifold 300 at a constant level.

The umbrella valve according to the present invention differs from other prior art umbrella valves in the material and dimensions, the material being Silastic liquid silicone rubber Q7-4840. The dimensions of the umbrella valve can be seen in Figure 3. In particular comparing Figure 3 to Figure 4A we see the present invention has a characteristic flap 312 which is thicker at its periphery than at its centre.

Due to the design used, the present invention umbrella valve does not act as a 'pop-off' valve like most umbrella valves as it is not designed to open at a specific pre-determined pressure. Most umbrella valves are designed to open at a specific 'cracking pressure', such as that shown in Figures 4A and 4B. Often prior art valves have a "cracking pressure which will increase as the flow threshold increases". The present invention is designed to open at a predetermined flow rate (in this specific application below 5 litres/minute) and keep on opening as the flow rate increases causing the pressure

to stay around a certain level as the flow increases. Most umbrella valves will open at a certain pressure and not open any further as the flow rate increases, causing the pressure to increase as the flow increases.

The improvement of the present invention is seen in Figure 5. Using a simple variable orifice 200 if the flow rate is changed between 5 and 15 litres per minute a dramatic change in PEEP will also occur. The PEEP range for the variable orifice 52 is 13 cmH_20. The best result obtained from prior art umbrella valves 54 was a PEEP range of 4.9cmH_20. The best result gained from the present invention 56 is a PEEP range of 2.8 cmH_20.

Referring to Figure 6 we see an alternate embodiment of the pressure regulator 134. Located between the inlet 302 and the orifice 306 is a PEEP valve 308, preferably in the umbrella valve described previously. Also included is an inlet 303 including a duck billed valve 305 which is normally closed, for introducing tubes down the trachea for suctioning, delivery of surfactant etc.

The manifold 300 is shaped to enable ease of use; it is designed to enable one handed operation. The manifold is wide and short and in this embodiment, shown in Figure 6, it is cylindrical. At the outlet to the neonate 304 connected to the manifold 300 is a flange 301. When used with a mask the flange 301 enables the operator to apply pressure to fluidicly seal the mask to the neonate's nose and mouth. The flange 301 also enables an operator to use a digit to occlude orifice 306 to vary pressure between the PIP and PEEP. The operator does this by placing their thumb and middle finger on the flange 301 at 309 and 311 and using their index finger to seal orifice 306. The orifice manifold 321 is at an angle shown at 309 to the manifold 300. This angle allows the index finger to be in a natural position to occlude orifice 306. The alternate embodiment of the pressure regulator 134 operates in the same way as the preferred embodiment described above.

New born neonates often lack surfactant in their lungs. The present invention when used with an endotracheal tube makes it easy to administer surfactant to a patient without the need to remove the breathing assistance apparatus from the patient. By using a syringe or other device known in the art the operator can administer surfactant to the neonate by

pushing the end of the syringe through the duck billed valve 305 located opposite the inlet to the neonate 301 and administrating the surfactant to the neonate

The duck billed valve 305 is normally fluidly sealed but upon insertion of the syringe opens to allow the end of the syringe to enter the interior of the manifold 307. The duck billed valve bills 320 seal around the end of the syringe keeping the manifold 300 sealed. The valve bills 320 are made out of silicone rubber or other suitable material as is known in the art. Because surfactant is a viscous fluid this is advantageous over administering surfactant using multi lumen endotracheal tubes.

The duck billed valve 305 can also be used to suction a neonate to remove airway secretions. Suctioning is performed using a catheter inserted through the duck billed valve down the endotracheal tube. The bills of the valve seal around the inserted catheter thereby maintaining airway pressure. The duckbilled valve is retained in a housing in such a way that any instrument inserted into the valve is guided directly into the top of an endotracheal tube (or nasal mask or other interface as are shown in the art), fitted at the outlet to the neonate 304, through the cylindrical tube guide 340.

When resuscitating or ventilating an infant it is desirable to ensure that the expired gases of the infant are not re-inspired by the infant. The portion of gases expired by the infant which can potentially be re-inspired is known as the dead-space. A baffle 342 is embodied in the present invention between the inlet 302 and the orifice 306. The baffle 342 provides a barrier to flow which extends from the top of the manifold to the top of a nasal mask (or endotracheal tube or other interface as are shown in the art). The inclusion of the baffle 342 causes the nominal flow path of gases to pass across the top of a mask (or similar) fitted to the manifold when the orifice 306 is in the unoccluded configuration. When the orifice 306 is occluded, the patient receives oxygenated gas from the inlet 302, and once the orifice 306 is unoccluded the expired gases are carried from the top of the mask to the outlet orifice 306 by the nominal flow of gas. This has the effect of greatly reducing the dead space within the manifold 307.

Figure 8 and Figure 9 illustrate an alternate embodiment of the pressure regulator 134. In this case the PEEP is variable as opposed to a set pop of valve. The delivered gases are varied between the PIP with orifice 334 occluded, and the PEEP with the orifice

334 unoccluded. There is a jet outlet 332 positioned between the inlet 328 and the orifice 332. The flow rate of the gases through the jet outlet 332 is controlled by the proximity of a screw on cap 324. The traveled distance of the screw on cap on the thread 325 determines the restriction to the orifice 332 and therefore varies the PEEP valve. The closer the screw on cap 324 to the jet outlet 332, the smaller the gas flow rate through the orifice 334. The manifold 330 as otherwise described in previous embodiments.

CLAIMS:

1. A pressure regulating device for use with a breathing assistance and/or resuscitation apparatus which conveys gases to an infant or neonate requiring resuscitation and/or breathing assistance, comprising or including:

a housing including an inlet and an outlet and an aperture, said inlet adapted to be in fluid communication or integrated with a breathing assistance and/or resuscitation apparatus and said outlet adapted to be in fluid communication with an infant,

a valve member disposed within said housing means, in the flow path between said inlet and said venting aperture, wherein the pressure of gases being below a predetermined level said valve member at least partially blocking said aperture and said gases thereby flowing from said inlet to said outlet, and wherein said gases being above said predetermined level said valve member allowing at least a portion of said gases to flow through said vent aperture,

wherein said predetermined level is substantially independent of the rate of flow of gases from said inlet to said outlet.

2. A device as claimed in claim 1 wherein said valve member comprises an elastomeric member including at least two configurations; in a first configuration substantially against a portion of said housing (herein the "valve seat") and a second configuration substantially spaced from said valve seat allowing a portion of the flow of gases from said inlet and/or said outlet to said aperture.

3. A device as claimed in claim 2 wherein said portion relative to the flow at said inlet is proportional to the level of flow at said inlet, thereby regulates the pressure at said outlet to a level substantially independent of flow rate.

4. A device as claimed in claim 2 or 3 wherein said elastomeric member adapted to switch from said first configuration to said second configuration at said predetermined level.

5. A device as claimed in claim 4 wherein said elastomeric member adapted such that as the flow rate increases in said second configuration a proportionally larger portion of the flow at the inlet is passed through said venting aperture then said outlet, to regulate the pressure at said outlet to substantially said predetermined level.

6. A device as claimed in claim 2 wherein said elastomeric member having a shaft adapted to engage said housing and a flap having a distal end adapted to engage said valve seat, said shaft attached to or integral with a proximate end of said flap, said proximal end being thinner in cross sectional width than said distal end.

7. A device as claimed in claim 6 wherein said elastomeric member is integrally molded from liquid silicon.

8. A device as claimed in claim 6 or 7 wherein the ratio of said proximal end thickness to said distal end thickness is 2:3.

9. A device as claimed in claim 8 wherein said shaft includes an annular flange adapted to retain at least said proximate end in relation to said aperture.

10. A device as claimed in claim 9 further comprising an occlusion opening in fluid communication with said aperture, the occlusion (or absence thereof) of said opening varying the delivered pressure to an infant between a desired PIP and PEEP respectively, said PEEP corresponding to said predetermined level.

11. A device for use with a breathing assistance apparatus which conveys gases to an infant or neonate requiring resuscitation and/or breathing assistance, comprising or including:

a housing including an inlet and an outlet and an aperture, said inlet adapted to be in fluid communication or integrated with a breathing assistance and/or resuscitation

apparatus and said outlet adapted to be in fluid communication with an infant, and

wherein said aperture adapted to receive a surfactant delivery means, and

sealing means adapted to prevent gas flow through said aperture and allow surfactant to be delivered to a patient through said aperture while providing breathing assistance.

12. A device as claimed in claim 11 wherein a pressure relief valve is in the flow path between said inlet and said venting aperture.

13. A device as claimed in claim 11 wherein said housing has a flange connected to the outlet to the patient such that in use the system can be manually operated one handed by an operator.

14. A device as claimed in claim 12 wherein said pressure relief valve comprises an elastomeric member including at least two configurations a first configuration substantially against a portion of said housing (herein the "valve seat") and a second configuration substantially spaced from said valve seat allowing a portion of the flow of gases from said inlet and/or said outlet to said aperture.

15. A device as claimed in claim 14 wherein said portion relative to the flow at said inlet is proportional to the level of flow at said inlet, thereby regulates the pressure at said outlet to a level substantially independent of flow rate.

16. A device as claimed in claim 13 wherein said elastomeric member adapted to switch from said first configuration to said second configuration at said predetermined level.

17. A device as claimed in claim 16 wherein said elastomeric member adapted such that as the flow rate increases in said second configuration a proportionally larger portion of the flow at the inlet is passed through said venting aperture then said outlet, to regulate

the pressure at said outlet to substantially said predetermined level.

18. A device as claimed in claim 11 wherein said sealing means is a duck billed valve.

19. A device as claimed in claim 10 or 11 wherein said aperture adapted to receive a surfactant delivery means and said outlet are substantially coaxial.

20. A pressure regulating device for use with a breathing assistance and/or resuscitation apparatus which conveys gases to an infant or a neonate requiring resuscitation and/or breathing assistance, comprising or including:

a housing including an inlet and an outlet and an aperture, said inlet adapted to be in fluid communication or integrated with a breathing assistance and/or resuscitation apparatus and said outlet adapted to be in fluid communication with an infant,

wherein said aperture is adapted to block or to vent or adapted to enable blocking or venting of a variable portion of gases passing through said housing from said inlet to said outlet through said aperture, and

a flange connected to said outlet adapted to engage a cushion or other means for substantially sealing the flow of gases to an infant or a neonate.

21. A device as claimed in claim 20 wherein said valve member comprises an elastomeric member adapted to lie in a first configuration substantially against a portion of said housing (herein the "valve seat") and by application of an external force a second configuration where said elastomeric member allowing a portion of the flow of gases from said inlet and/or said outlet to said venting aperture.

22. A device as claimed in claim 20 wherein said portion relative to the flow at said inlet is proportional to the level of flow at said inlet, thereby regulates the pressure at said outlet to a level relatively independent of flow rate.

23. A device as claimed in claim 21 wherein said elastomeric member adapted to

switch from said first configuration to said second configuration at said predetermined level, said external force comprising the pressure of the gases flowing from said inlet to said outlet.

24. A device as claimed in claim 23 wherein said elastomeric member adapted such that as the flow rate increases in said second configuration a proportionally larger portion of the flow at the inlet is passed through said venting aperture then said outlet, to regulate the pressure at said outlet to substantially said predetermined level.

25. A device as claimed in claim 20 wherein said housing also includes an aperture adapted to receive a surfactant delivery means and sealing means adapted to in use allow surfactant to be delivered to a patient through said aperture without said aperture fluidicly communicating with said interior of said housing while providing breathing assistance.

26. A device as claimed in claim 25 wherein said sealing means is a duck billed valve.

27. A device as claimed in claim 26 wherein said aperture adapted to receive a surfactant delivery means and said outlet are substantially coaxial.

28. A device as claimed in claim 20 wherein said housing is substantially cylindrical.

29. A device as claimed in claim 20 wherein said housing is part cylindrical and part frustoconical.

30. A device as claimed in claim 29 wherein the width of said housing at said flange is less than the height of said housing.

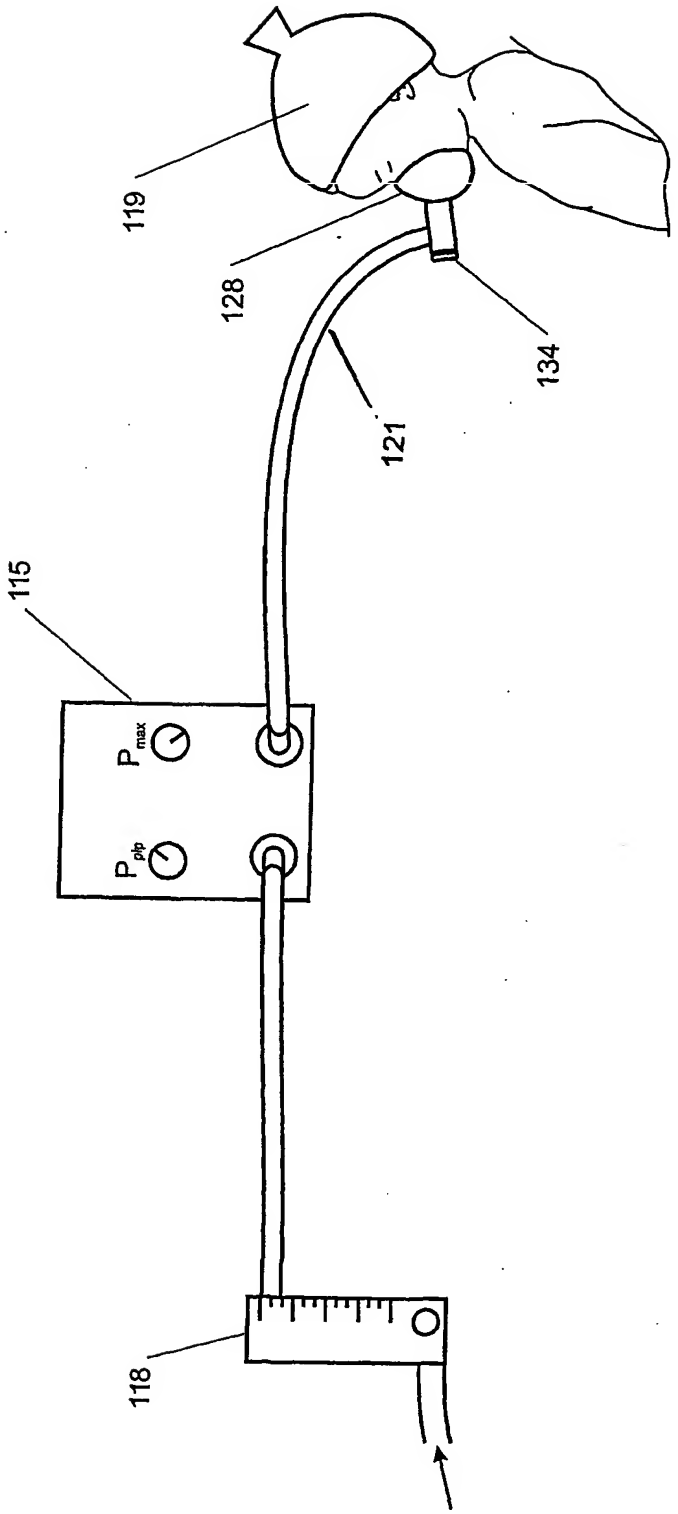

FIGURE 1

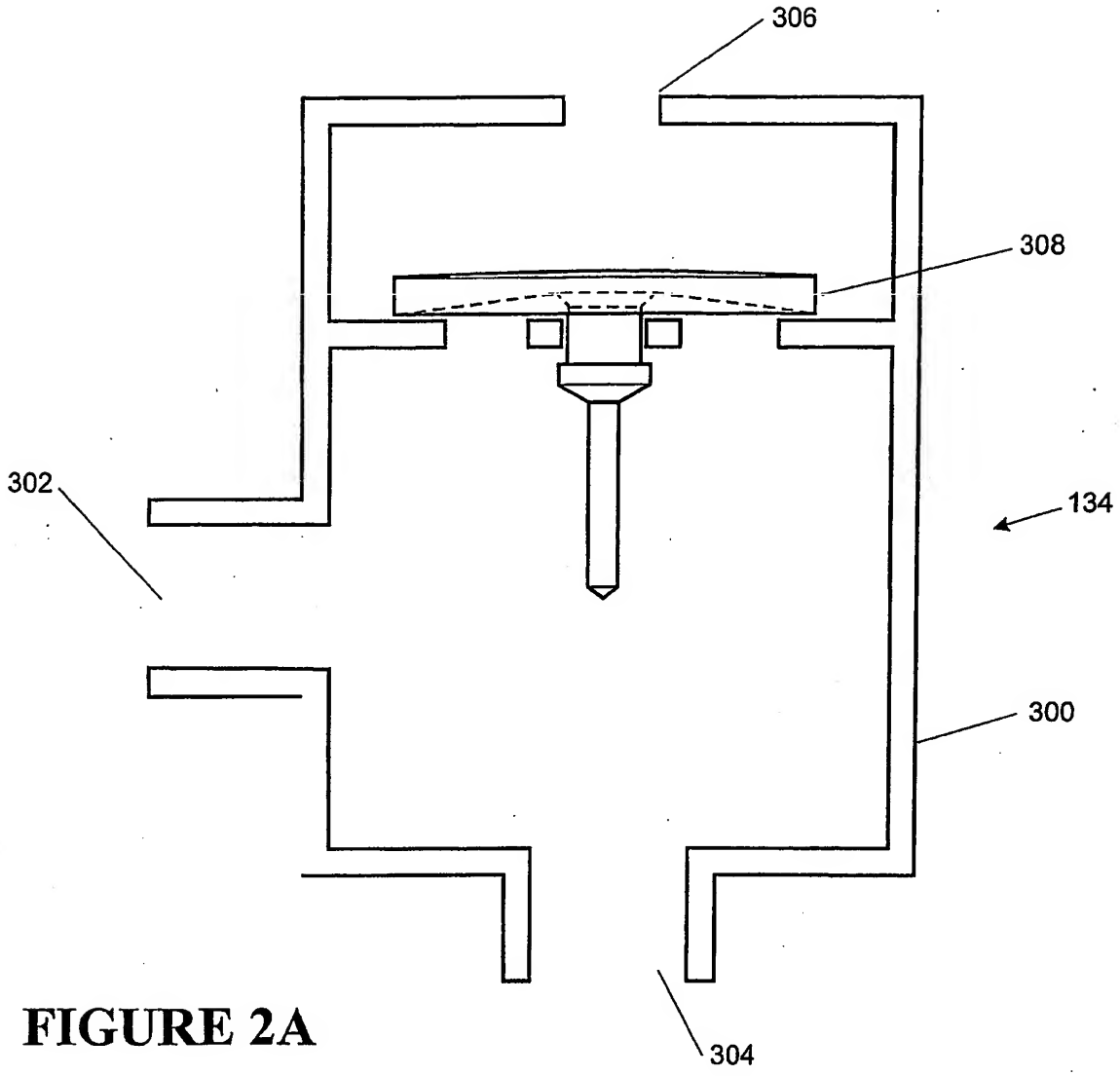

FIGURE 2A

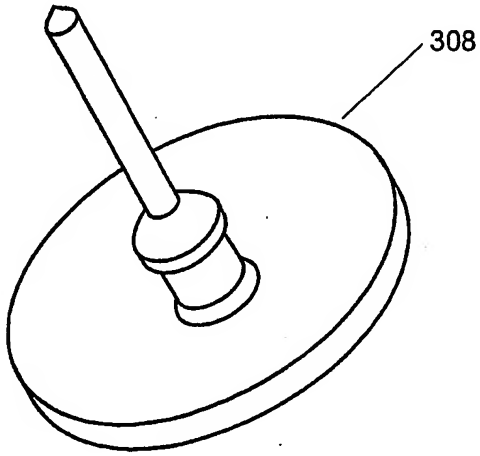

FIGURE 2B

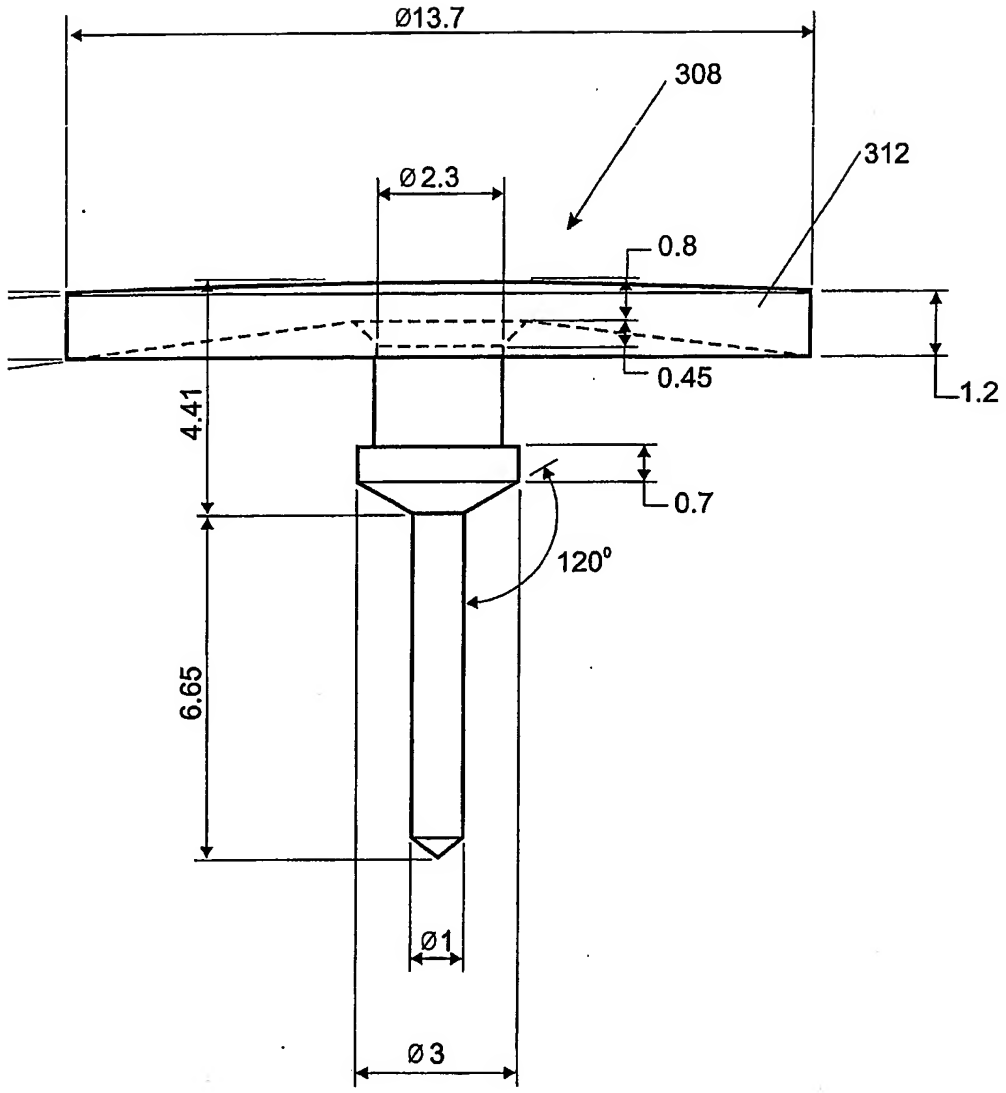

FIGURE 3

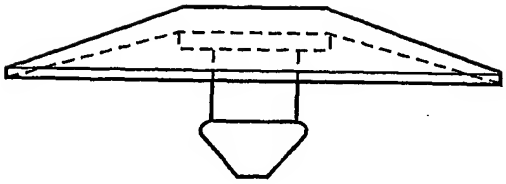

FIGURE 4A

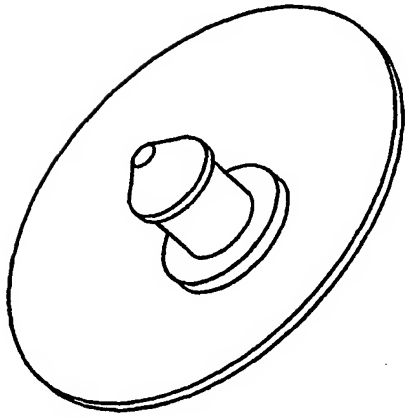

FIGURE 4B

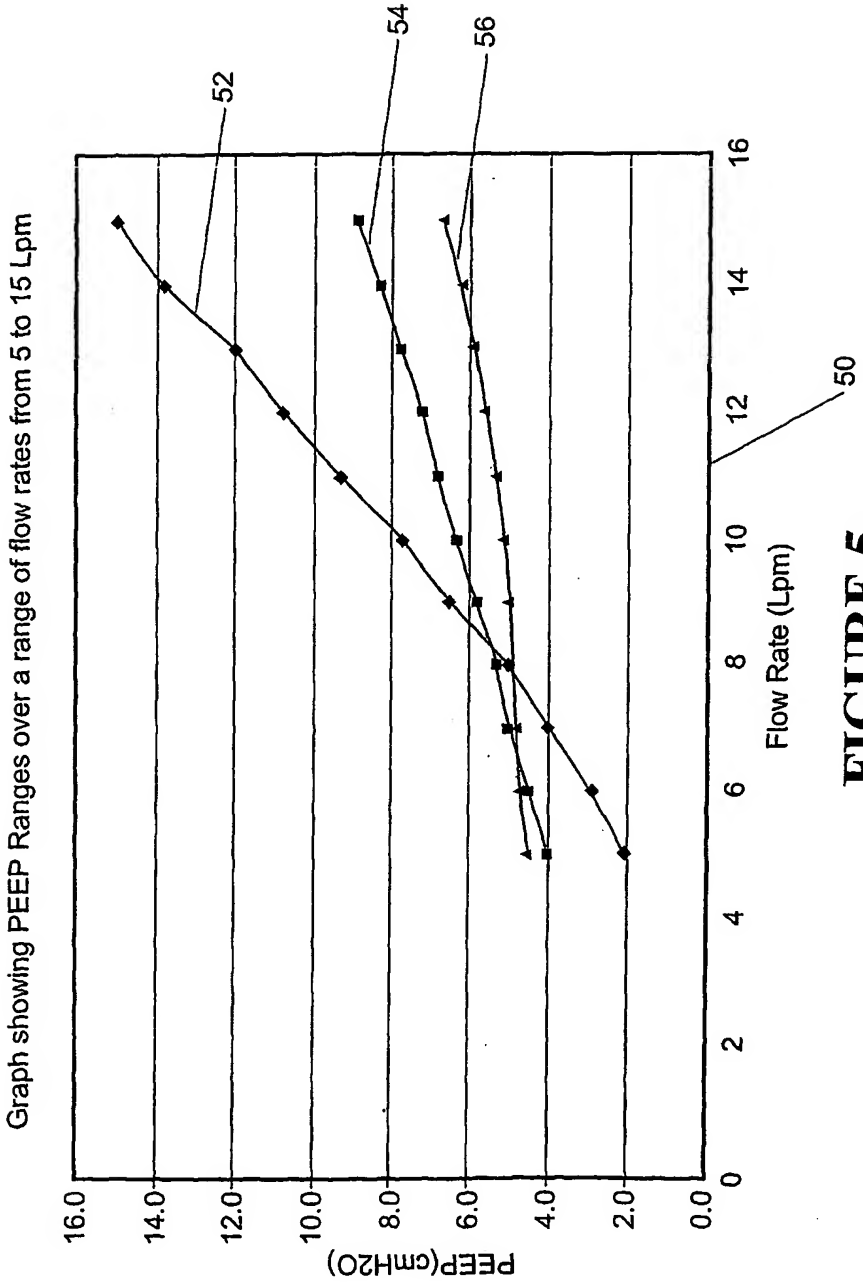
Graph showing PEEP Ranges over a range of flow rates from 5 to 15 Lpm
PEEP(cmH2O)
16.0
14.0
12.0
10.0
8.0
6.0
4.0
2.0
0.0
Flow Rate (Lpm)
0
2
4
6
8
10
12
14
16
50
52
54
56

FIGURE 5

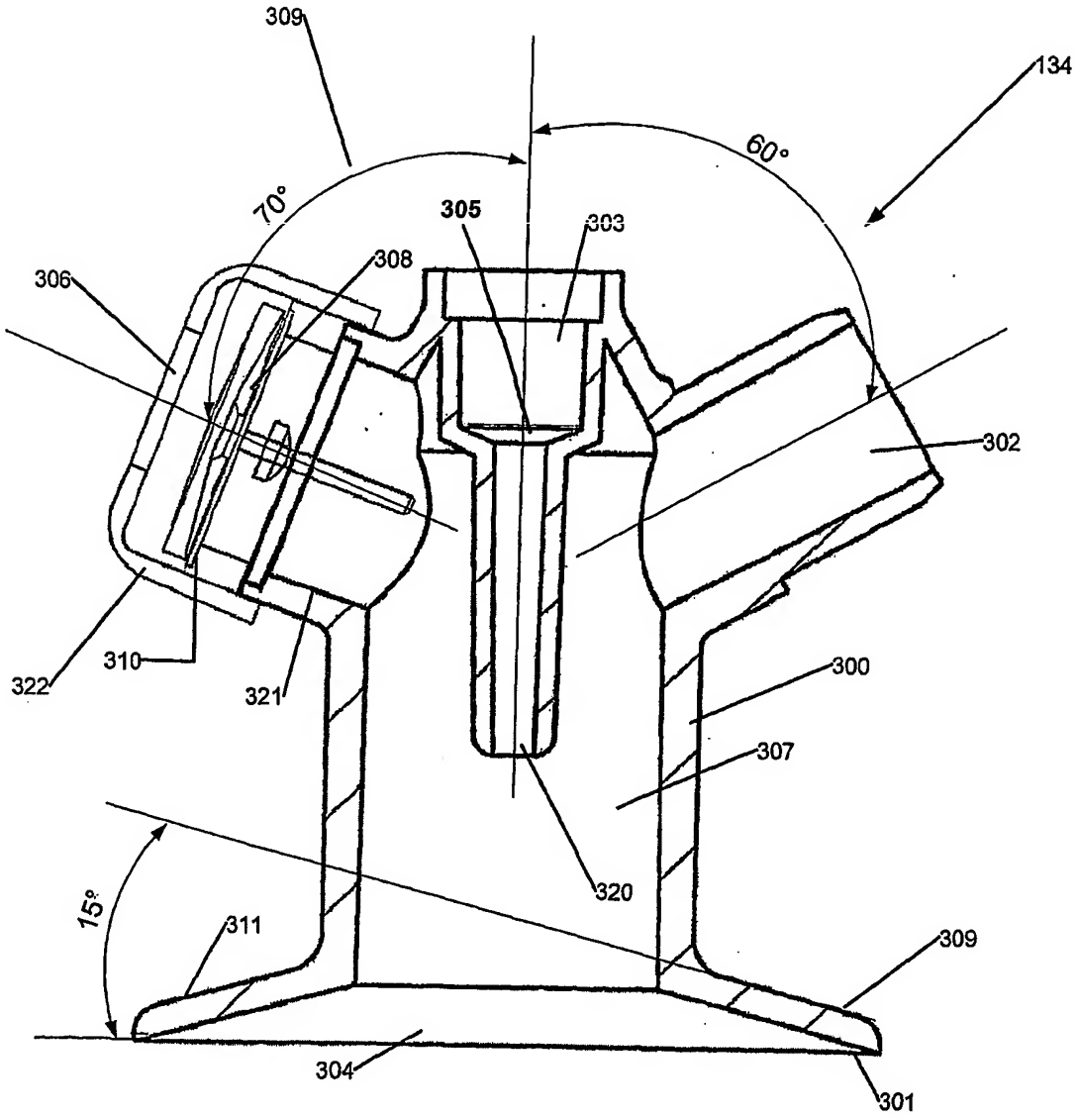
309
134
60°
70°
305
303
308
306
302
322
310
321
300
307
320
15°
311
309
304
301

Figure 6

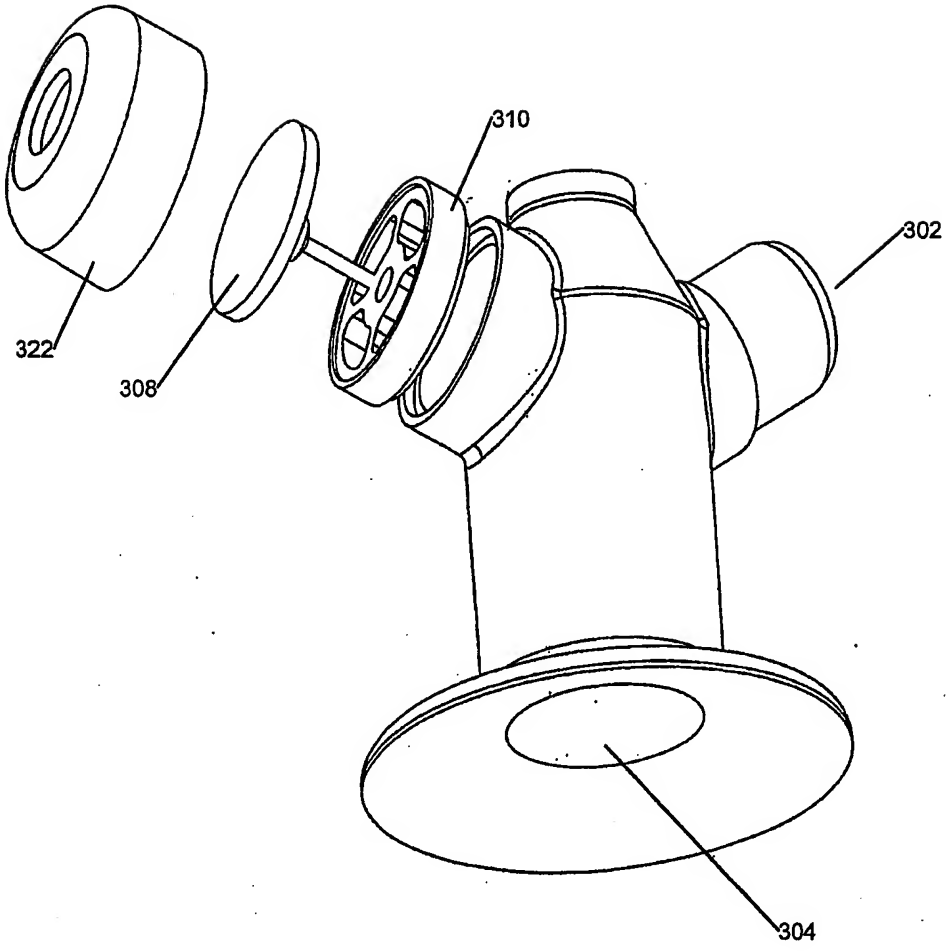

Figure 7

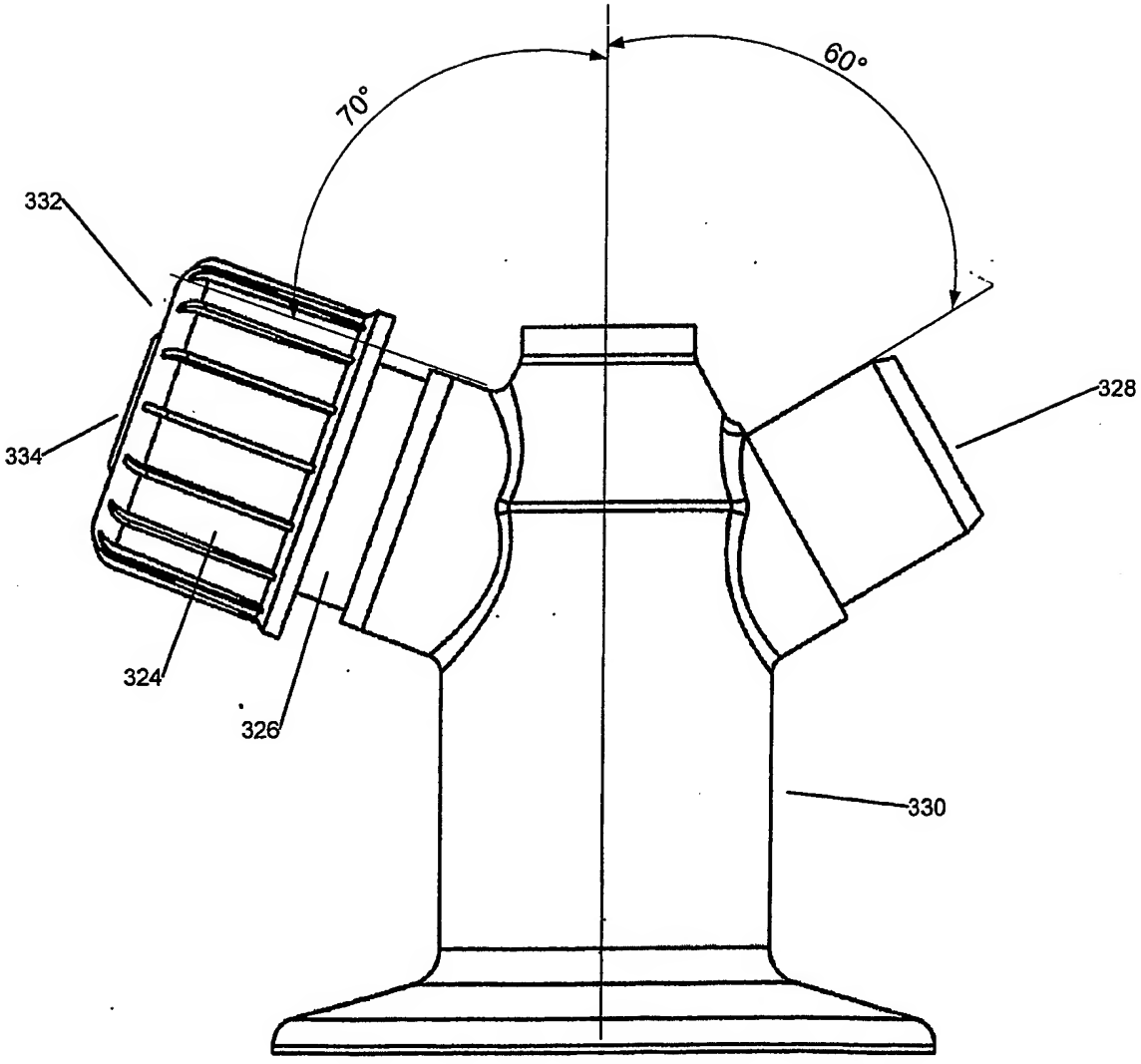

Figure 8

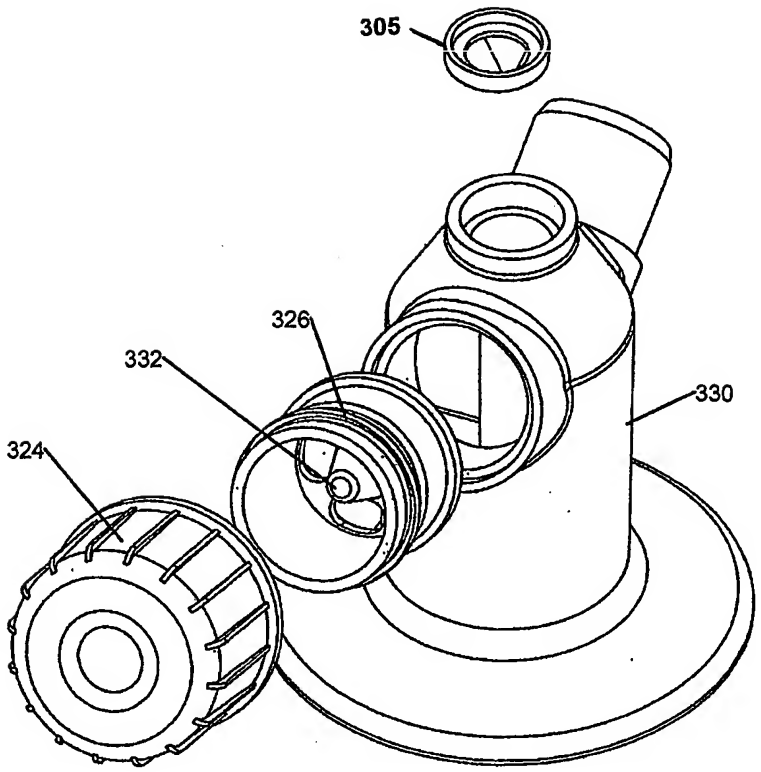

Figure 9

INTERNATIONAL SEARCH REPORT

International application No.
PCT/NZ03/00014

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl. [7]: A61M 16/20

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
Refer electronic databases below

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
DWPI + keywords: respiratory, valve, umbrella and similar terms

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	GB 2 222 778 A (SABRE SAFETY LTD.) 21 March 1990 Abstract and Figure 1	1-10, 20-30
X	US 4,655,213 (RAPOPORT et al) 7 April 1987 Figure 2 and column 2 lines 30 to 34	1, 20
X	WO 00/22985 (CHILDREN'S HOSPITAL, INC) Page 9 lines 8 to 11	1, 20

[X] Further documents are listed in the continuation of Box C [X] See patent family annex

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
5 May 2003	11 JUN 2003
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized officer **JAGDISH BOKIL** Telephone No : (02) 6283 2371

INTERNATIONAL SEARCH REPORT

International application No.
PCT/NZ03/00014

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,762,063 (COATES et al) 9 June 1998 Abstract	11-19
X	US 5,207,220 (LONG) 4 May 1993 column 5 lines 33 to 46 and figure	11
A	US 1,162,416 (TETER) 30 November 1915 Figure 2 and page 1 lines 101 to 103	
A	US 1,632,449 (McKESSON) 17 July 1924 Figure 1	
A	US 6,006,748 (HOLLIS) 28 December 1999 Figure 1	
A	FR 1 580 403 (S.A. FERNEZ) 5 September 1969 Figures 1-5	
A	FR 2 709 066 A1(SCHEGERIN) 24 February 1995 Figure 1	
A	Internet disclosure from "PressCut Industries"- Technical Bulletin. 25 January 2001 URL: <http:web.archive.org/web/20010125074600/http://presscut.com/pctb9603.htm>	

INTERNATIONAL SEARCH REPORT

International application No.
PCT/NZ03/00014

Box I **Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)**

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos :

because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos :

because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos :

because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

Box II **Observations where unity of invention is lacking (Continuation of item 3 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows:

First invention: claims 1-10
Second invention: claims 11-19
Third invention: claims 20-30

see additional sheet

1. ☒ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

Supplemental Box
(To be used when the space in any of Boxes I to VIII is not sufficient)

Continuation of Box No: II

The international application does not comply with the requirements of unity because it does not relate to one invention or group of inventions so linked as to form a single general inventive concept. In coming to this conclusion the International Searching Authority has found that there are three different inventions as follows:

1. Claims 1-10 are directed towards a pressure regulating device for use with a breathing assistance device comprising a valve member which vents gases when pressure is above a predetermined level. It is considered that a valve member which vents gases when pressure is above a predetermined level comprises a first "special technical feature".

2. Claims 11-19 are directed towards a device for use with a breathing assistance apparatus, the device comprising a housing including an aperture adapted to receive a surfactant delivery means. It is considered that a housing including an aperture adapted to receive a surfactant delivery means comprises a second "special technical feature".

3. Claims 20-30 are directed towards a pressure regulating device comprising a housing including an inlet, an outlet and an aperture for venting gases and a flange connected to outlet for sealing the flow of gases to an infant or neonate. It is considered that a flange connected to outlet for sealing the flow of gases to an infant or neonate comprises a third "special technical feature".

Groups 1 and 3 of claims are not linked as to form a single general inventive concept, that is, they do not share any special technical features. The common concept linking together these groups of claims is a pressure regulating device with an aperture for venting gases. However this concept is not novel in the light of common general knowledge of breathing assistance devices. Therefore these claims do not relate to one invention only, *a posteriori.*

Groups 1 and 3 of claims do not share any of the special technical features with group 2, therefore a technical relationship between the inventions does not exist. Accordingly the claims do not relate to one invention or to a single inventive concept, *a priori.*

It is considered that the inventions of groups 1 and 3 are sufficiently similar that they can both be searched with only a moderate amount of extra effort than would be required to search either one. Consequently only one additional search fee is invited.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/NZ03/00014

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member					
GB	2222778	NONE					
US	4655213	DE	3435565	GB	2147506	JP	60227770
WO	0022985	NONE					
US	1162416	NONE					
US	5207220	NONE					
US	5762063	NONE					
US	1632449	NONE					
US	6006748	AU	41018/97				
FR	1580403	NONE					
FR	2709066	NONE					

END OF ANNEX